



[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1253

[Docket No. CPSC-2019-0023]

Children's Toys and Child Care Articles: Determinations Regarding ASTM F963 Elements and Phthalates for Unfinished Manufactured Fibers

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (CPSC) is proposing a rule to determine that certain unfinished manufactured fibers would not contain the ASTM F963 elements or specified phthalates that exceed the limits set forth under the CPSC's statutes and regulations for children's toys and child care articles. Based on these proposed determinations, the specified unfinished manufactured fibers would not be required to have third party testing for compliance with the requirements of the ASTM F963 elements or phthalates for children's toys and child care articles.

DATES: Submit comments by **[INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2019-0023 by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: www.regulations.gov. Follow the instructions for submitting comments. The CPSC does not accept comments submitted by electronic mail (e-mail), except through

www.regulations.gov. The CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: www.regulations.gov, and insert the docket number CPSC-2019-0023, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Jacqueline Campbell, Senior Textile Technologist, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850: telephone 301-987-2024; email: jcampbell@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

1. Third Party Testing and Burden Reduction

Section 14(a) of the Consumer Product Safety Act, (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires that manufacturers of products subject to a consumer product safety rule or similar rule, ban, standard, or regulation enforced by the CPSC, must certify that the product complies with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). For children's products, certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* Public Law No. 112-28 (August 12, 2011) directed the CPSC to seek comment on "opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation." Public Law No. 112-28 also authorized the Commission to issue new or revised third party testing regulations if the Commission determines "that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations." *Id.* 2063(d)(3)(B).

To provide opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulations, the CPSC assessed whether children's toys and child care articles manufactured with seven manufactured fibers: polyester (polyethylene terephthalate, PET), nylon, polyurethane (spandex), viscose rayon, natural rubber latex, acrylic, and modacrylic, would comply with CPSC's requirements for ASTM F963

elements or phthalates. If the Commission determines that such materials will comply with CPSC's requirements with a high degree of assurance, manufacturers do not need to have those materials tested by a third party testing laboratory to issue a Children's Product Certificate (CPC).

2. ASTM F963 Elements

Section 106 of the CPSIA provides that the provisions of ASTM International, *Consumer Safety Specifications for Toy Safety* (ASTM F963), shall be considered to be consumer product safety standards issued by the Commission.¹ 15 U.S.C. 2056b. The Commission has issued a rule that incorporates by reference the relevant provisions of ASTM F963. 16 CFR part 1250.² Thus, children's toys subject to ASTM F963 must be tested by a CPSC-accepted third party laboratory and demonstrate compliance with all applicable CPSC requirements for the manufacturer to issue a CPC before the children's toys can be entered into commerce.

Section 4.3.5 of ASTM F963 requires that surface coating materials and accessible substrates of children's toys that can be sucked, mouthed, or ingested³ must comply with the solubility limits of eight elements given in Table 1 of the toy standard.

¹ ASTM F963 is a consumer product safety standard, except for section 4.2 and Annex 4, or any provision that restates or incorporates an existing mandatory standard or ban promulgated by the Commission or by statute.

² The Commission is not proposing to incorporate ASTM F963 by reference into part 1253.

³ ASTM F963 contains the following note regarding the scope of the solubility requirement: NOTE 4—For the purposes of this requirement, the following criteria are considered reasonably appropriate for the classification of children's toys or parts likely to be sucked, mouthed or ingested: (1) All toy parts intended to be mouthed or contact food or drink, components of children's toys which are cosmetics, and components of writing instruments categorized as children's toys; (2) Children's toys intended for children less than 6 years of age, that is, all accessible parts and components where there is a probability that those parts and components may come into contact with the mouth.

The materials and their solubility limits are shown in Table 1. We refer to these eight elements as “ASTM F963 elements.”

Table 1: Maximum Soluble Migrated Element in ppm (mg/kg) for Surface Coatings and Substrates Included as Part of a Toy	
Elements	Solubility Limit, (ppm) ⁴
Antimony (Sb)	60
Arsenic (As)	25
Barium (Ba)	1000
Cadmium (Cd)	75
Chromium (Cr)	60
Lead (Pb)	90
Mercury (Hg)	60
Selenium (Se)	500

The third party testing burden could be reduced only if all elements listed in section 4.3.5 have concentrations below their solubility limits. Because third party conformity assessment bodies typically run one test for all of the ASTM F963 elements, no testing burden reduction would be achieved if any one of the elements requires testing.

To alleviate some of the third party testing burdens associated with the ASTM F963 elements in the accessible component parts of children's toys, the Commission determined that certain unfinished and untreated trunk wood does not contain ASTM

⁴ The method to assess the solubility of a listed element is detailed in section 8.3.2, *Method to Dissolve Soluble Matter for Surface Coatings*, of ASTM F963. Modeling clays included as part of a toy have different solubility limits for several of the elements.

F963 elements that would exceed the limits specified in section 106 of the CPSIA. Based on this determination, unfinished and untreated trunk wood would not require third party testing for the ASTM F963 elements. 16 CFR part 1251. The Commission also has determined that untreated and unfinished engineered wood products would not require third party testing for the ASTM elements or specified phthalates (discussed below) for children's products, children's toys, and child care products. 16 CFR part 1252.

3. Phthalates

Section 108(a) of the CPSIA permanently prohibits the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of any "children's toy or child care article" that contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or butyl benzyl phthalate (BBP). 15 U.S.C. 2057c(a).

The CPSIA required the Commission to appoint a Chronic Hazard Advisory Panel (CHAP) to "study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles." 15 U.S.C. 2057c(b)(2). The CHAP issued its report in July 2014. On October 27, 2017, the Commission published a final rule in the *Federal Register*, "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates," 82 FR 49938, prohibiting children's toys and child care articles containing concentrations greater than 0.1 percent of: di-(2-ethylhexyl) phthalate (DEHP); dibutyl phthalate (DBP); benzyl butyl phthalate (BBP); diisononyl phthalate (DINP); diisobutyl phthalate (DIBP); di-n-pentyl phthalate (DPENP); di-n-hexyl phthalate (DHEXP); or dicyclohexyl phthalate (DCHP). These restrictions apply to any plasticized component part of a children's toy or child care

article or any other component part of a children's toy or child care article that is made of other materials that may contain phthalates. The phthalates prohibitions are set forth in 16 CFR part 1307.

Tests for phthalate concentration are among the most expensive certification tests to conduct on a product, and each accessible component part subject to section 108 of the CPSIA must be tested. Third party testing burden reductions can occur only if each phthalate's concentration is below 0.1 percent (1000 ppm). Because laboratories typically run one test for all of the specified phthalates, no testing burden reduction likely is achieved if any one of the phthalates requires compliance testing.

B. Contractor's Research

The CPSC contracted with the Toxicology Excellence for Risk Assessment (TERA, or the contractor) to conduct literature reviews on the production of certain undyed manufactured fibers and to evaluate whether the specified manufactured fibers potentially contain (1) any of the specified chemical elements that are included in the toy standard in concentrations⁵ exceeding specified limits, or (2) any of 10 specified phthalates in concentrations greater than 0.1 percent (1000 ppm). TERA researched the following manufactured fibers: polyester (polyethylene terephthalate, PET), nylon, polyurethane (spandex), viscose rayon, natural rubber latex, acrylic, and modacrylic. Staff reviewed the information provided in the TERA report, *Exposure Assessment: Potential for the Presence of Phthalates and Other Specified Elements in Undyed*

⁵ Although the ASTM F963-17 standard for chemical elements is a solubility requirement, TERA researched total content, in part because of the expected availability of content data versus solubility data and because content is a conservative stand-in for chemical solubility (*i.e.*, the content of a chemical is the same value as one hundred percent solubility of the chemical from solubility testing).

Manufactured Fibers and their Colorants (the report, Task 17).⁶ TERA's Task 17 report formed the basis for the proposed unfinished manufactured fiber determinations. For more detailed information on the Task 17 report and staff analysis please see the staff briefing package. https://www.cpsc.gov/s3fs-public/Draft%20NPR-%20Children%27s%20Toys%20and%20Child%20Care%20Articles-%20Determinations%20Regar....pdf?IB4eKjJ_meZH1vdT5uQeojG8FfYGeqD9.

All of the fibers covered in the Task 17 report are manufactured and do not naturally occur in a fiber state. Although their raw starting materials may be different, these fibers are generally extruded into a fiber form. In many cases, additional chemicals may be added before the extrusion process so that the chemicals are embedded in the fiber structure. To better understand where the specified phthalates or ASTM elements may be present, TERA documented the fiber chemical characteristics, manufacturing processes, typical colorants, and any other relevant information found through their search strategy.

C. CPSC Staff Analysis of TERA Task 17 Report

CPSC staff reviewed the TERA Task 17 Report. CPSC staff also examined TERA's source references to better understand the report's findings. The Task 17 Report focused on the possibility of the ASTM F963 elements and specified phthalates being present in seven manufactured fiber types.

Unfinished fibers

⁶ Task Order 17, Contract Number CPSC-D-12-0001. Available at: <https://www.cpsc.gov/s3fs-public/TERA%20Task17%20Report%20Phthalates%20and%20ASTM%20Elements%20in%20Manufactured%20Fibers.pdf>.

The TERA report found one significant use of an ASTM element in unfinished manufactured fibers: antimony in the production of polyester (PET) fibers at concentrations of about 150–300 ppm, amounts that would exceed the solubility limit specified in ASTM F963. Staff does not have information identifying the amount of the antimony that is soluble when tested according to ASTM F963. PET fiber is widely used in consumer textile products, including children’s toys. The contractor report did not identify any other instances of the use of ASTM elements or phthalates in the routine manufacturing processes for the specified unfinished fibers.

Compliance to the ASTM F963 standard can be demonstrated by measuring the chemical content of a material—if the total content for a specific element does not exceed the solubility limit, then it must be the case that the solubility requirement is met. Because information about solubility or migration of chemicals from products or materials is rarely available in the scientific literature or other data sources, staff relies on information about chemical content to understand possible uses and presence of chemicals in products. If sufficient solubility testing data were available, especially if data show low levels of migration, such data may help inform decisions about testing requirements under the ASTM F963 standard.

In addition to intentional use of the specified chemicals, staff considered whether contaminants or impurities may be present in unfinished fibers, yarns, or fabrics. In the review of the contractor report, the reports referenced by the contractor, and other reference materials, staff has not found any information or data that suggest contaminants would be present in fibers at significant levels. Reported contaminant levels, such as for arsenic, chromium, mercury, or cadmium, are no higher than a few parts per million.

Staff believes that contaminants or impurities are unintentional (*i.e.*, not added by the manufacturer intentionally), and largely represent the ubiquity of some substances in the environment at trace levels or general industrial practices and conditions. Given the available data and staff's understanding of the raw materials and manufacturing practices for the fibers currently under consideration, staff concludes that any impurities will be at levels well below the relevant limits for this proceeding.

Dyed or Finished Fibers (or Fibers with Chemical Additives Pre-Fiber Formation)

Colorants, such as dyes, often contain metals in their structure. The contractor report cited the use of mercury, arsenic, barium, or chromium in dyes or dye auxiliaries. For example, chrome dyes are a type of acid dye that can be used on nylon fibers and contains chromium to form a complex between the dye and the fiber. Because the use of these metals is not necessarily limited to a specific dye class or fiber type, staff cannot rule out the use of these metals at concentrations greater than those specified in ASTM F963 without more information. Furthermore, the contractor report cited the potential use of some of the specified phthalates as dye auxiliaries or carriers for pigments. Although some of the findings may have been with products not necessarily within the scope of the subject rules, the mechanism by which colorants are applied to fibers could be extended to those products.

Finishes may also be added at the fiber (yarn or fabric) stage to impart desirable characteristics. The contractor report highlighted the use of antimony compounds as flame retardants. Other chemicals of interest may be used in finished fiber (yarn or fabric); however, those finishes were not within the scope of the contractor report, and

more information is necessary to consider whether determinations for finished fiber (yarn or fabric) are appropriate. Staff notes that in the case of the ASTM elements (excluding lead, which has separate specific restrictions under the CPSIA), the restriction in the ASTM F963 standard is based on solubility; *i.e.*, migration of the elements from the product or material.

Recycled Content

TERA did not examine the potential use of recycled materials in the subject manufactured fibers. Staff is aware that recycled content is present in some textile fibers; however, staff does not know the extent to which recycled content can be expected in products within the scope of the ASTM F963 elements or phthalates requirements. Due to findings in the contractor report on colorants and finishes in manufactured fibers, staff does not recommend determinations for fibers with recycled content unless such content was from unfinished recycled materials.

D. Determinations for Unfinished Manufactured Fibers

1. Legal Requirements for a Determination

As discussed in section A.1. of the preamble, section 14(a)(2) of the CPSA requires third party testing for children's products that are subject to a children's product safety rule. 15 U.S.C. 2063(a)(2). Children's toys must comply with the limits on the ASTM F963 elements incorporated in 16 CFR part 1250. Children's toys and child care articles must comply with the phthalates prohibitions in section 108 of the CPSIA and 16 CFR part 1307. 15 U.S.C. 2057c. In response to statutory direction, the Commission has investigated approaches that would reduce the burden of third party testing while also assuring compliance with CPSC requirements. As part of that endeavor, the Commission

has considered whether certain materials used in children's toys and child care articles would not require third party testing.

To issue a determination that a manufactured fiber does not require third party testing, the Commission must have sufficient evidence to conclude that the product consistently complies with the CPSC requirements to which the manufactured fiber is subject so that third party testing is unnecessary to provide a high degree of assurance of compliance. Under 16 CFR part 1107 section 1107.2, "a high degree of assurance" is defined as "an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture."

For accessible component parts of children's toys and child care articles subject to sections 106 and 108 of the CPSIA and 16 CFR part 1307, compliance to the specified content limits is always required, irrespective of any testing exemptions. Thus, a manufacturer or importer who certifies a children's toy or child care article, must assure the product's compliance. The presence of the ASTM F963 elements or the specified phthalates does not have to be intended to require compliance. The presence of these chemicals, whether for any functional purpose, as a trace material, or as a contaminant, must be in concentrations less than the specified content or solubility limits for the material to be compliant. Additionally, the manufacturer or importer must have a high degree of assurance that the product has not been adulterated or contaminated to an extent that would render it noncompliant. For example, if a manufacturer or importer is relying on a determination that a manufactured fiber does not contain the ASTM F963 elements or specified phthalates in concentrations greater than the specified limits in a children's

toy or child care article, the manufacturer must ensure that the manufactured fiber is one on which a determination has been made.

Furthermore, under the proposed rule, any determinations that are made on manufactured fibers are limited to unfinished manufactured fibers. Children's toys and child care articles made from these manufactured fibers may have other materials that are applied to or added on to the manufactured fiber after it is manufactured, such as colorants and flame retardants. Such component parts fall outside of the scope of the proposed determinations and would be subject to third party testing requirements, unless the component part has a separate determination that does not require third-party testing for certification purposes. Finally, even if a determination is in effect and third party testing is not required, a certifier must still issue a certificate.

The six unfinished manufactured fibers for which determinations are proposed for the ASTM F963 elements are: nylon, polyurethane (spandex), viscose rayon, acrylic, and modacrylic, and natural rubber latex. Based on staff's review of the TERA report as discussed in section C. of the preamble, the Commission is proposing determinations that there is a high degree of assurance that these unfinished manufactured fibers will not contain the ASTM F963 elements in concentrations greater than their specified limits. We note that based on staff's review of the Task 17 report we are not proposing a determination that polyester (PET) fiber does not contain any of the ASTM F963 elements in concentrations greater than their specified solubility limits due to findings in the contractor report regarding the use of antimony compounds in polyester manufacturing.

The Commission is also proposing determinations for seven unfinished manufactured fibers for the specified phthalates prohibitions: polyester (PET), nylon, polyurethane (spandex), viscose rayon, acrylic, and modacrylic, and natural rubber latex. Based on staff's review of the TERA report as discussed in section C. of the preamble, the Commission is proposing determinations that there is a high degree of assurance that these unfinished manufactured fibers will not contain the prohibited phthalates in concentrations greater than their specified limits.

These determinations would mean that, for the specified unfinished manufactured fibers, third party testing is not required to assure compliance with sections 106 and 108 of the CPSIA and 16 CFR part 1307. The Commission proposes to make these determinations to reduce the third party testing burden on children's product certifiers while continuing to assure compliance.

2. Statutory Authority

Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, to implement the CPSIA. Public Law 110-314, sec. 3, Aug. 14, 2008. Section 14 of the CPSA, which was amended by the CPSIA, requires third party testing for children's products subject to a children's product safety rule. 15 U.S.C. 2063(a)(2). Section 14(d)(3)(B) of the CPSA, as amended by Public Law 112-28, gives the Commission the authority to "prescribe new or revised third party testing regulations if it determines that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations." *Id.* 2063(d)(3)(B). These statutory provisions authorize the Commission to propose a rule determining that certain unfinished

manufactured fibers do not contain the ASTM F963 elements and the specified prohibited phthalates in concentrations greater than their specified limits, and thus, are not required to be third party tested to assure compliance with sections 106 and 108 of the CPSIA and 16 CFR part 1307.

The proposed determinations would relieve manufacturers using the specified unfinished manufactured fibers from the third party testing requirements of section 14 of the CPSA for purposes of supporting the required certification. However, the proposed determinations would not be applicable to any other manufactured fibers beyond those listed in the proposed rule. The proposed determinations would only relieve the manufacturers' obligation to have the specified unfinished manufactured fibers tested by a CPSC-accepted third party conformity assessment body. Children's toys and child care articles must still comply with the substantive content limits in sections 106 and 108 of the CPSIA and 16 CFR part 1307 regardless of any relief on third party testing requirements.

3. Description of the Proposed Rule

This proposed rule would create a new Part 1253 for "Children's toys and Child Care Articles: Determinations Regarding the ASTM F963 Elements and Phthalates for Unfinished Manufactured Fibers." The proposed rule would determine that the specified unfinished manufactured fibers do not contain any of the ASTM F963 elements in excess of specified concentrations, and any of the phthalates (DEHP, DBP, BBP, DINP, DIBP, DPENP, DHEXP, and DCHP) prohibited by statute or regulation in concentrations greater than 0.1 percent.

Section 1253.1(a) of the proposed rule explains the statutorily-created requirements for limiting the ASTM F963 elements in children's toys under the CPSIA and the third party testing requirements for children's toys.

Section 1253.1(b) of the proposed rule explains the statutory and regulatory requirements limiting phthalates for children's toys and child care articles under the CPSIA and the third party testing requirements for children's toys and child care articles.

Section 1253.2(a) of the proposed rule would provide a definition of the term unfinished manufactured fiber that would apply to part 1253.

Section 1253.2(b) of the proposed rule would establish the Commission's determinations that specified unfinished manufactured fibers do not exceed the solubility limits for ASTM F963 elements with a high degree of assurance as that term is defined in 16 CFR part 1107.

Section 1253.2(c) of the proposed rule would establish the Commission's determinations that specified unfinished manufactured fibers do not exceed the phthalates content limits with a high degree of assurance as that term is defined in 16 CFR part 1107.

Section 1253.2(d) of the proposed rule states that accessible component parts of children's toys and child care articles made with the specified unfinished manufactured fibers specifically listed in the determinations in proposed § 1253.3(b) and (c) are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

Section 1253.2(e) of the proposed rule states that accessible component parts of children's toys and child care articles that are not specifically listed in the determinations

in proposed § 1253.3(b) and (c) are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

4. Requested Comments on the Proposed Rule

The Commission seeks comments on all aspects of the proposed rule. In particular, comments on the following topics are welcome.

- Are there any data or examples that indicate that the manufactured fibers identified in the proposed rule can and do contain the ASTM F963 elements (besides the identified use of antimony in PET) or prohibited phthalates at levels that are not compliant in an unfinished state? Please provide data supporting your assertion.
- The TERA Task 17 Report identified the use of antimony, an ASTM F963 element, as a catalyst used to manufacture PET. Although TERA looked for the presence and total concentration of antimony, the ASTM F963-17 requirement is for the concentration that migrates out of the subject material. Please provide any information that supports or refutes the claim that antimony will not be present in concentrations greater than the specified limits in PET fiber in an unfinished state without colorants. Please provide any information that antimony will not migrate out of polyester in concentrations greater than the specified limits in PET fiber in an unfinished state with no colorants.
- Are there any data or examples that the colorants or other finishes used for the manufactured fibers identified in the proposed rule never contain the ASTM F963 elements or prohibited phthalates at levels that are not compliant? Please provide

data supporting your assertion. These data may be by type of dye, a specific dye, by fiber type, or some other relevant grouping.

- Are there any data or examples that the use of recycled content in the manufactured fibers identified in the proposed rule never contain the ASTM F963 elements or prohibited phthalates at levels that are not compliant? Please provide data supporting your assertion. These data may be by fiber type, product type, or some other relevant grouping.
- In addition to the manufactured fibers within scope of this study, are there other manufactured fibers widely used in children's toys and childcare articles that have not been identified in the proposed rule that do not, and will not contain the ASTM F963 elements or prohibited phthalates? Please provide supporting data to show that these manufactured fibers do not and will not contain the ASTM F963 elements or prohibited phthalates in concentrations above the mandatory limits?

E. Effective Date

The Administrative Procedure Act (APA) generally requires that a substantive rule must be published not less than 30 days before its effective date. 5 U.S.C. 553(d)(1). Because the proposed rule would provide relief from existing testing requirements under the CPSIA, the Commission proposes a 30 day effective date for the final rule.

F. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act (RFA) requires that agencies review a proposed rule for the rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial

regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency is required to publish a notice of proposed rulemaking, unless the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. The IRFA must describe the impact of the proposed rule on small entities and identify any alternatives which accomplish the statutory objectives and may reduce the significant economic impact of the proposed rule on small entities. We provide a summary of the IRFA.

2. Small Entities to Which the Proposed Rule Would Apply

The proposed rule would apply to small entities that manufacture or import children's toys and child care articles that contain the specified manufactured fibers. The chemical elements in the ASTM F963 toy safety standard and the specified phthalates apply to the particular children's products specified in the respective requirements. The phthalates prohibitions apply to children's toys and child care articles. Regarding the specified manufactured fibers (or yarns or fabrics) in the children's toy category, products potentially affected by a Commission determination about phthalate content may include coverings or fill of stuffed, plush, or other soft toys, doll clothes, puzzle mats or other play mats, and other similar toys. Under the child care article category, products potentially affected by a Commission determination about phthalate content may include sleepwear, bibs, and other products that facilitate sleeping or feeding. The chemical requirements in the ASTM F963 toy safety standard cover accessible substrates of toys that can be sucked, mouthed, or ingested. The specified manufactured fibers (or yarns or fabrics) could be used in coverings or fill of stuffed, plush, or other soft toys, doll clothes, puzzle mats or other play mats, and other similar

toys.

The rule would apply to small entities that manufacture or import children's toys or child care articles that contain accessible polyester (PET), nylon, natural latex rubber, polyurethane (spandex), rayon, acrylic, and modacrylic component parts. Toy manufacturers are classified in North American Industry Classification System (NAICS) category 339930 (Doll, Toy, and Game Manufacturing). According to the U.S. Bureau of the Census, in 2015 there were 566 toy manufacturers in the United States, of which 562 had fewer than 500 employees and would be considered small entities according to the SBA criteria.⁷ Of the small manufacturers, 347 had fewer than five employees.

Toy importers may be either wholesale merchants or retailers. The proposed rule would not apply to toy wholesalers or retailers if they obtain their merchandise from domestic manufacturers or importers and do not import toys or child care articles themselves. Toy wholesalers are classified in NAICS category 423920 (Toy and Hobby Goods and Supplies Merchant Wholesalers). According to the U.S. Bureau of the Census, there were 2,009 firms in this category in 2015. Of these, 1,937 had fewer than 100 employees and would be considered small businesses, according to SBA criteria. Toy retailers are classified in NAICS category 451120 (Hobby, Toy, and Game Stores). There could be about 4,632 toy retailers that would meet the SBA criteria to be considered a small entity.⁸ Although importers are responsible for certifying the

⁷ U.S. Bureau of the Census, "Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2015," County Business Patterns. Available at: https://www2.census.gov/programs-surveys/susb/tables/2015/us_6digitnaics_2015.xlsx

⁸ The SBA considers a toy retailer (NAICS 451120) to be a small entity if its annual sales are less than \$27.5 million. According to the U.S. Bureau of the Census, in 2012, the average receipts for toy manufacturers with more than 500 employees was almost \$900 million. The average receipts for the next largest category for which summary data were published, toy retailers with at least 100 but fewer than 500

children's products that they import, they may rely upon third party testing performed by their foreign suppliers for purposes of certification. We do not know the number of small toy wholesalers or retailers that import toys, as opposed to obtaining their product from domestic sources. We also do not know the number of small importers that must obtain or pay for the third party testing of their products.

The phthalates regulation also applies to manufacturers and importers of child care articles. Child care articles include many types of products for which the CPSC has recently promulgated or proposed new or amended mandatory safety standards. Under the child care article category, products potentially affected by a Commission determination about phthalate content of unfinished manufactured fibers may include bedside sleepers, sleepwear, bibs, and other products that facilitate sleep or feeding. Several types of these child care products likely use the types of manufactured fibers that are addressed by the proposed rule. In its recent market research, CPSC staff identified 364 suppliers of these products that would be considered small according to criteria established by the SBA.⁹ Additionally, there could be other child care articles, not listed above, for which CPSC has not yet developed a mandatory or proposed standard, but which nevertheless are covered by the phthalate requirements.

Although the number of small businesses that supply children's toys or child care articles to the U.S. market might be close to 10,000, we do not know the number that actually supply products with the unfinished manufactured fibers in accessible

employees, was about \$10 million. There were 4,647 firms in this NAICS category, of which 4,632 had fewer than 500 employees. (U.S. Census Bureau, Number of Firms, Number of Establishments, Employment, Annual Payroll, and Estimated Receipts by Enterprise Employment Size for the United States, All Industries: 2012.)

⁹ Krishnan, Charu S., Memorandum: Determinations that Certain Plastics Will Not Contain Specified Phthalates: Regulatory Flexibility Analysis, Directorate for Economic Analysis, CPSC. June 26, 2017.

component parts. We also do not know the number of children's toys and child care articles that contain these fibers. Nevertheless, based on the number of domestic toy manufacturers that are classified as small businesses (according to SBA size standards and data provided by the U.S. Bureau of the Census) and evidence that the specified fibers could be used extensively in toys and child care articles, we believe a substantial number of small entities would be positively impacted by the proposed rule.

3. Reporting, Recordkeeping, and Other Compliance Requirements and Impact on Small Businesses

The proposed rule would not impose any reporting, recordkeeping, or other compliance requirements on small entities. In fact, the proposed rule would eliminate a requirement that third party testing be done, resulting in a small reduction in some of the recordkeeping burden under 16 CFR parts 1107 and 1109 because manufacturers would no longer have to maintain records of third party tests for the component parts manufactured from the specified unfinished manufactured fibers.

The impact of the determinations on small businesses would be to reduce the burden of third party testing for the ASTM F963 elements and the specified phthalates, and would be expected to be entirely beneficial. Based on published invoices and price lists, the cost of a third-party test for the ASTM F963 elements ranges from around \$60 in China, up to around \$190 in the United States using Inductively Coupled Plasma (ICP) testing. This cost can be greatly reduced with the use of high definition X-Ray fluorescence spectrometry (HDXRF), which is an acceptable method for certification of third party testing for the presence of the ASTM elements. The cost can be reduced to about \$40 per component.

The cost of phthalate testing is relatively high: between about \$125 and \$350 per component, depending upon where the testing is conducted and any discounts that are applicable. Because one product might have multiple components that require testing, the cost of testing a single product for phthalates could exceed \$1,000.

Moreover, more than one sample might have to be tested to provide a high degree of assurance of compliance with the requirements for testing. To the extent that small businesses have lower production or sales volumes than larger businesses, these determinations would be expected to have a disproportionately beneficial impact on small businesses. This beneficial impact is due to spreading the costs of the testing over fewer units; and the benefit of the Commission making the determinations would be greater on a per unit basis for small businesses. Additionally, some testing laboratories may offer their larger customers discounts that might not be available to small businesses that need fewer third-party tests. Making the determinations for these manufactured fibers could significantly benefit a substantial number of firms.

However, it is possible that the benefit of making the determinations could be less than staff expects. Although the manufactured fibers are widely used, the determinations are limited to unfinished fibers, which might be less widely used. Additionally, some firms might have been able to substantially reduce their third party testing costs by using component part testing as allowed by 16 CFR 1109, so the marginal benefit to manufacturers from making the determinations might be low. Also, some firms have reduced their testing costs by using XRF or HDXRF technology, which is less expensive than ICP, and would reduce the marginal benefit of these determinations. Finally, some firms, particularly importers, might not know the specific fibers used in the products they

import or whether fibers are unfinished and might opt to conduct the testing anyway to ensure that the products do not violate the requirements.

In summary, although there are a substantial number of small entities that manufacture or import children's toys and childcare articles in which manufactured fibers could be used, we do not have data on the number or the extent to which unfinished manufactured fibers are used in these products. Therefore, we cannot determine whether the reduced burden would be significant for a substantial number of the small entities. We welcome public comments on the potential impact of the proposed rule on small entities. Comments are especially welcome on the following topics:

- The extent to which the specified unfinished manufactured fibers are used in children's toys, and child care articles, especially those manufactured or imported by small firms;
- The potential reduction in third party testing costs that might be provided by the Commission making the determinations, including the extent to which component part testing is already being used and the current cost of testing components made from these unfinished manufactured fibers for compliance with the ASTM elements and phthalate requirements;
- Any situations or conditions in the proposed rule that would make it difficult to use the determinations to reduce third party testing costs; and
- Although the CPSC staff expects that the impact of the proposed rule will be entirely beneficial, any potential negative impacts of the proposed rule.

4. Alternatives Considered to Reduce the Burden on Small Entities

Under section 603(c) of the RFA, an initial regulatory flexibility analysis should “contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant impact of the proposed rule on small entities.” Because the proposed rule is intended to reduce the cost of third party testing on small businesses and will not impose any additional burden, the Commission did not consider alternatives to the proposed rule that would reduce the burden of this rule on small businesses.

G. Environmental Considerations

The Commission’s regulations provide a categorical exclusion for Commission rules from any requirement to prepare an environmental assessment or an environmental impact statement because they “have little or no potential for affecting the human environment.” 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required. The Commission’s regulations state that safety standards for products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(1). Nothing in this rule alters that expectation.

List of Subjects in 16 CFR Part 1253

Business and industry, Consumer protection, Imports, Infants and children, Product testing and certification, Toys.

For the reasons stated in the preamble, the Commission proposes to amend title 16 of the CFR to add part 1253 to read as follows:

PART 1253—Children’s toys and Child Care Articles: Determinations Regarding the ASTM F963 elements and Phthalates for Unfinished Manufactured Fibers

Sec.

1253.1 Children’s toys and child care articles containing the ASTM F963 elements and phthalates in manufactured fibers and testing requirements.

1253.2 Determinations for unfinished manufactured fibers.

Authority: Sec. 3, Pub. L. 110-314, 122 Stat. 3016; 15 U.S.C. 2063(d)(3)(B).

§ 1253.1 Children’s toys and child care articles containing the ASTM F963 elements and phthalates in manufactured fibers and testing requirements.

(a) Section 106 of the CPSIA made the provisions of ASTM F963, Consumer Product Safety Specifications for Toy Safety, a mandatory consumer product safety standard. 16 CFR part 1250 codified these provisions by incorporating by reference ASTM F963, see 16 CFR1250.1. Among the mandated provisions is section 4.3.5 of ASTM F963, which requires that surface coating materials and accessible substrates of children’s toys that can be sucked, mouthed, or ingested, must comply with solubility limits that the toy standard establishes for eight elements. Materials used in children’s toys subject to section 4.3.5 of the toy standard must comply with the third party testing requirements of section 14(a)(2) of the CPSA, unless listed in § 1253.2.

(b) Section 108(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) permanently prohibits any children's toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). In accordance with section 108(b)(3) of the CPSIA, 16 CFR part 1307 prohibits any children's toy or child care article that

contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisobutyl phthalate (DIBP), di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP), or dicyclohexyl phthalate (DCHP). Materials used in children's toys and child care articles subject to section 108(a) of the CPSIA and 16 CFR part 1307 must comply with the third party testing requirements of section 14(a)(2) of the Consumer Product Safety Act (CPSA), unless listed in § 1253.2.

§ 1253.2 Determinations for unfinished manufactured fibers.

(a) The following definition for an unfinished manufactured fiber applies for this part 1253. An unfinished manufactured fiber is one that has no chemical additives beyond those required to manufacture the fiber. For unfinished manufactured fibers as defined in this rule, the unfinished manufactured fiber is free of any chemical additives added to impart color or some desirable performance property, such as flame retardancy.

(b) The following unfinished manufactured fibers do not exceed the ASTM F963 elements solubility limits set forth in 16 CFR part 1250 with a high degree of assurance as that term is defined in 16 CFR part 1107:

- (1) Nylon;
- (2) Polyurethane (Spandex);
- (3) Viscose Rayon;
- (4) Acrylic and Modacrylic; and
- (5) Natural Rubber Latex.

(c) The following unfinished manufactured fibers do not exceed the phthalates content limits set forth in 16 CFR part 1307 with a high degree of assurance as that term is defined in 16 CFR part 1107:

(1) Polyester (polyethylene terephthalate, PET);

(2) Nylon;

(3) Polyurethane (Spandex);

(4) Viscose Rayon;

(5) Acrylic and Modacrylic; and

(6) Natural Rubber Latex.

(d) Accessible component parts of children's toys and child care articles made with the unfinished manufactured fibers, listed in paragraphs (b) and (c) of this section are not required to be third-party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

(e) Accessible component parts of children's toys and child care articles made with manufactured fibers not listed in paragraphs (b) and (c) of this section are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

Alberta E. Mills, Secretary
Consumer Product Safety Commission

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